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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Garvey et al**

Application No: **09/512,829** Group Art Unit: **1624**

Filed: **February 25, 2000** Examiner: **D. Rao**

For: **Methods using Proton Pump Inhibitors and Nitric Oxide Donors**

Attorney Docket No: **102258.284**

Assistant Commissioner of Patents
Washington, DC 20231

Provisional Response to Restriction Requirement and Request for Reconsideration of Restriction Requirement Under 37 C.F.R. § 1.143

This response is submitted in reply to the Restriction Requirement dated February 26, 2002, for which a response is due on or before March 26, 2002. No fee is believed to be due; however, the Commissioner is authorized to charge any necessary fees to Deposit Account No. 08-0219 to maintain the pendency of the present application.

I. Request for Reconsideration of Restriction Requirement

Under 37 C. F. R. § 1.143, Applicants respectfully request reconsideration of the restriction requirement dated February 26, 2002.

The examiner restricted the invention as follows:

Group I	claims 50, 51, 64, 36-45 and 79-84	method of improving the gastroprotective properties of a proton pump inhibitor[1]
Group II	claims 59-60 (in part), 36-45 and 79-84	method for preventing or treating a gastrointestinal disorder with the exception of *H. pylori* associated disease using a proton pump inhibitor[2]

[1] The inventions in Examiner's Groups I-V are all directed to the methods of use of a proton pump inhibitor compound **in combinati n with** a compound that donates, transfers or releases nitric oxide, induces the production of endogenous nitric oxide or endothelium-derived relaxing factor, stimulates endogenous synthesis of nitric oxide or is a substrate for nitric oxide synthase.

[2] Applicants respectfully note that *H. pylori* is included in the gastrointestinal disorders in claim 59

Group III	claims 66, 36-45 and 79-84	method for decreasing or reversing gastrointestinal toxicity using a proton pump inhibitor
Group IV	claims 68, 59-60 (in part), 36-45 and 79-84	method for preventing or treating an infection caused by *H. pylori* or a *H. pylori* associated disease using a proton pump inhibitor
Group V	Claims 71-72, 36-45 and 79-84	method for treating a viral infection using a proton pump inhibitor

The pending claims are directed to the methods of using a proton pump inhibitor in combination with a compound that donates, transfers or releases nitric oxide, induces the production of endogenous nitric oxide or endothelium-derived relaxing factor, stimulates endogenous synthesis of nitric oxide or is a substrate for nitric oxide synthase. Independent claims 50, 59, 64, 66 and 68 are directed to methods of use for **gastrointestinal disorders** by administration of a proton pump inhibitor in combination with a NO^3 donor as follows:

claims 50 and 64	method of improving the **gastroprotective** properties of a proton pump inhibitor i.e. **a gastrointestinal disorder**
claim 59	method for preventing or treating a **gastrointestinal disorder**
claim 66	method for decreasing or reversing **gastrointestinal** toxicity or facilitation ulcer healing **a gastrointestinal disorder**
claim 68	method for treating an infection caused by *H. pylori* or a *H. pylori* associated disease, i.e., **a gastrointestinal disorder**

Applicant's respectfully submit that independent claims 50, 59, 64, 66 and 68 and claims dependent thereon (i.e., Examiner's Groups I-IV) are all related as they are directed to methods for the treatment and/or prevention of a **gastrointestinal disorder** by administration of a proton

pump inhibitor in combination with a NO donor. Thus, the restriction requirement is not proper. To show that the inventions are distinct, the Examiner must show either that (1) there is a separate classification of the claims; (2) a separate status in the art when they are classifiable together; or (3) a different field of search.

Moreover, a search of the prior art for the gastrointestinal disorders of Group I would necessarily encompass a search of the prior art for the gastrointestinal disorders in Groups II-IV. Thus, the prior art for Group I will also be the same prior art for Groups II-IV. Additionally, the prior art search already conducted by the Examiner for compositions comprising a proton pump inhibitor in combination with a NO donor would be the same prior art for the methods of use for compositions comprising a proton pump inhibitor in combination with a NO donor.

II. Proposed restriction requirement

Applicants respectfully propose the following restriction requirement for consideration:

Group I:	claims 50, 51, 59, 60, 64, 66, 68, 36-45 (in part) and 79-84 (in part)	method for treating and/or preventing a gastrointestinal disorder using a proton pump inhibitor and a NO donor
Group II	claims 71-72, 36-45 (in part) and 79-84 (in part)	methods for treating a viral infection using a proton pump inhibitor and a NO donor

III. Provisional Response to Restriction Requirement

Applicants provisionally elect Group I, with traverse, drawn to methods of improving the gastroprotective properties, the anti-*Helicobacter pylori* or the antacid properties of a proton pump inhibitor.

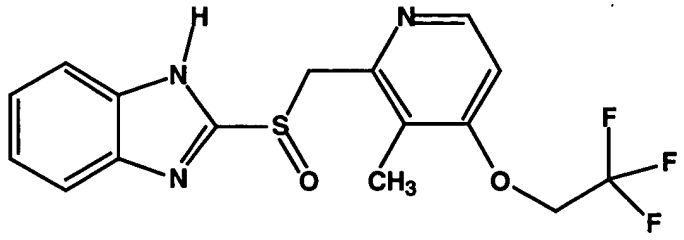
IV. Election of Species

In response to the election of species requirement, Applicants provisionally elect, with traverse, lansoprazole as the proton pump inhibitor, and S-nitrosoglutathione as the compound that donates transfers or releases nitric oxide, induces the production of endogenous nitric oxide or endothelium derived relaxing factor, or is a substrate for nitric oxide synthase. This election

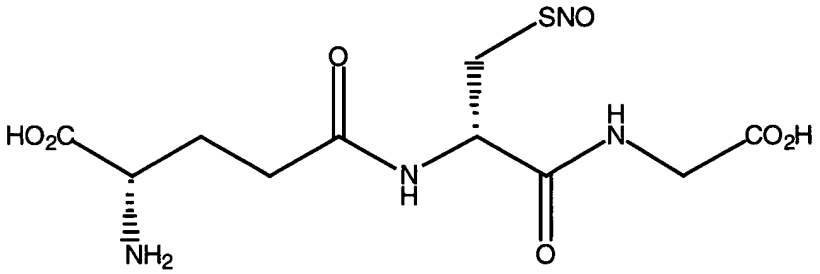
[3] Throughout NO donor refers to a compound that donates transfers or releases nitric oxide, or induces the production of endogenous nitric oxide or endothelium derived relaxing factor, or is a substrate for nitric oxide synthase.

of species is identical to Applicant's election of species in reply to the Restriction Requirement dated June 19, 2001.

Lansoprazole has the following structure:



S-nitrosoglutathione has the following structure:



V. Information Disclosure Statement

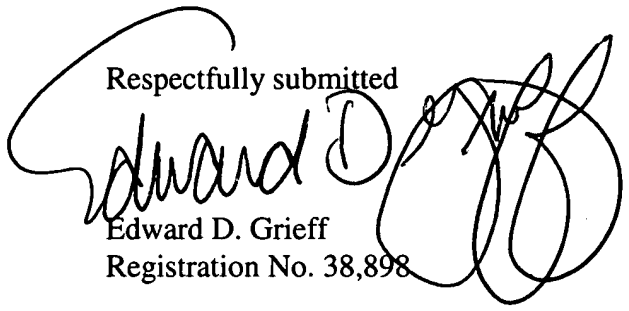
Applicants respectfully request that the Examiner acknowledge the references cited on the Information Disclosure Statements and PTO-1449 Forms filed April 20, 2000, and December 13, 2001. A copy of the PTO-1449 Forms from these previously-filed Information Disclosure Statements is submitted herewith for the Examiner's convenience. Applicants respectfully request that the Examiner initial and return a copy of the PTO-1449 Forms with the next communication from the Office.

VI. Conclusion

Applicants respectfully request that the restriction requirement be withdrawn, and replaced with Applicant's proposed restriction requirement.

An early and favorable consideration and allowance of the pending claims is respectfully requested.

Respectfully submitted



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